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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427
24247	7590	05/06/2004	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/081,953

Applicant(s)

HENNEN ET AL.

Examiner

Stacy B Chen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's amendment and response filed February 23, 2004 is acknowledged and entered. In view of Applicant's arguments, the rejection of claims 1-3, 7-16 and 18-22 under 35 U.S.C. 102(b) as anticipated by Tokoro (5,080,895) is withdrawn. The rejection of claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over Tokoro (5,080,895) in view of Kirkpatrick *et al.* (5,840,700) is withdrawn in view of Applicant's arguments. Applicant's substantive arguments are primarily directed to the failure of the Tokoro reference to disclose antigens that would have elicited a T-cell mediated immune response. Therefore, the Tokoro reference does not teach or inherently possess the transfer factor composition used in the method in the instant claims.
2. Upon further consideration of the pending claims, the following new grounds of rejection are made. The Office regrets any inconvenience to Applicant.

### ***Claim Rejections - 35 USC § 112***

3. The rejection of claim 22 under 35 U.S.C. 112, second paragraph is maintained for reasons of record. Applicant's arguments have been carefully considered but fail to persuade withdrawal of the rejection. Applicant argues that the strength of the immune system can be measured by its response to certain stimuli, particularly the swelling of mouse footpads. In response, the claim fails to point out what exactly is strengthened in the immune system. One would not know what to measure to detect a strengthened immune system. The swelling of mouse footpads indicates an increased response of T-cells to transfer factor. If Applicant intends

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to measure a T-cell response, then the claim should indicate that the T-cell response is increased (along with comparative basis).

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 and dependent claims 2-10 and 13-22 are unclear because the claims recite “method for treating an animal”, but fail indicate what is being treated. The claims indicate a result of the treatment, but that result is not correlated with the treatment of anything in particular.
- Claim 11 and dependent claim 12, the claimed method comprises administering transfer factor to treat a disease state associated with infection by a pathogen. The meaning of “disease state” is unclear? How is it distinguished from “disease”? How does one treat a “disease state”? Clarification is required.

#### ***Claim Rejections - 35 USC § 102***

4. Claims 1-3, 7-13 and 15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (5,367,054). The claims are drawn to a method for treating an animal with transfer factor to elicit a T-cell mediated immune response. The method comprises administering an egg extract that contains transfer factor obtained from immunizing an egg-producing animal with an antigen and eliciting a T-cell mediated immune response. The transfer factor has a molecular weight of about 4-5 kD and can be administered orally. Transfer factor can be from an amphibian, reptilian, fish or bird.

Lee teaches a method for isolating and purifying immunoglobulins or fragments thereof or other biologically active factors from non-immune or immune egg yolk extracts (abstract). Lee's immune eggs are collected from any egg-producing member of the avian, reptile, amphibian or fish family, which have been immunized (col. 4, lines 58-63). The antigens that can be used to immunize the egg-producing subject include bacteria, viruses, fungi, parasites and yeasts (col. 7, lines 45-65). Although Lee does not mention the presence of transfer factor, it would inherently be present in Lee's egg extract because the egg-producing subjects are exposed to antigens that are capable of eliciting a T-cell mediated immune response. Further, hens, amphibians, reptiles and fish are exposed to a plurality of natural antigens that are present in the environment regardless of human-controlled exposure to antigens (vaccination). Lee teaches that the products purified from the eggs are for pharmaceutical purposes such as passive immunization or as a health food ingredient (column 3, lines 31-40). As a health food ingredient, the transfer factor would be combined with a carrier (food) and configured for oral administration. The molecular weight of transfer factor is an inherent property of transfer factor. While the preamble of the claim 1 and dependent claims is not specifically taught, the mere consumption or passive immunization with Lee's product inherently anticipates "treating an animal with transfer factor to elicit a T-cell mediated immune response", since transfer factor is inherently present in Lee's product.

***Claim Rejections - 35 USC § 103***

5. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (5,367,054) as applied to claims 1-3, 7-13 and 15-22 above, and further in view of Taylor

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(5,001,225). The claims are drawn to a method for treating an animal with transfer factor to elicit a T-cell mediated immune response. The transfer factor is administered to an animal nasally, parenterally or topically. The teachings of Lee are summarized above. Lee is silent on the specific routes of immunization using the egg extract product.

However, Taylor discloses general methods well-known in the art for vaccines and passive immunizations, such as parenteral, oral, intranasal, intravenous, intramuscular, topical or subcutaneous (abstract, column 15, lines 37-69, and column 16, lines 1-14). It would have been obvious to administer Lee's egg extract via the routes of administration disclosed by Taylor. One would have been motivated by Lee's teaching that egg extracts can be used in passive immunization (column 3, lines 31-40). One would have had a reasonable expectation of success that the administration of Lee's product via the routes disclosed by Taylor would have worked to elicit a T-cell mediated immune response in the recipient of the egg extract, because Lee's product contains transfer factor and the administration of transfer factor would elicit the T-cell response.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (5,367,054) as applied to claims 1-3, 7-13 and 15-22 above, and further in view of Dekich (*Poultry Science*, 1998, 77:1176-1180). The claim is drawn to a method for treating an animal with transfer factor to elicit a T-cell mediated immune response. The method comprises administering an egg extract that contains transfer factor obtained from immunizing an egg-producing animal with an antigen and eliciting a T-cell mediated immune response. The transfer factor molecules are

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specific for at least one antigen, such as Newcastle Disease virus. Lee is silent on specific viral antigens used to immunize egg-producing animals.

However, Dekich discloses several diseases that are treated/prevented in the boiler industry. Respiratory diseases include Newcastle disease, infectious bronchitis and infectious laryngotracheitis (page 1177, first column). Passive immunization techniques have been used for all three diseases. One would have been motivated to immunize Lee's egg-producing animals, such as chickens, with antigens associated with Newcastle disease because Dekich teaches that Newcastle disease is common among chickens. One would have been motivated by Lee's suggestion that viral antigens can be chosen to hyperimmunize egg-producing animals (Lee, column 7, line 55, and column 8, lines 25-27). One would have had a reasonable expectation of success that the immunization of Lee's egg-producing animal with Newcastle disease virus antigen would have resulted in a T-cell mediated immune response, and thus transfer factor would have been produced.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

7. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive

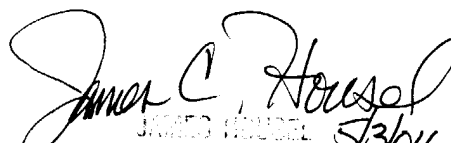
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transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (571) 272-0896. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy B. Chen  
April 22, 2004



JAMES HOUSEL 5/3/04  
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